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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,941	02/21/2006	Michael Horstmann	RO4150US (#90568)	7611
28672 7590 09/09/2009 D. PETER HOCHBERG CO. L.P.A. 1940 EAST 6TH STREET CLEVELAND, OH 44114			EXAMINER MERCIER, MELISSA S	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 09/09/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,941	<b>Applicant(s)</b> HORSTMANN ET AL.	
	<b>Examiner</b> MELISSA S. MERCIER	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-18 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-10 and 12-18 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

#### **Combination of active substances**

- a. a combination of a dopamine agonist and an anti-cholinergically active substance
- b. a combination of L-dopa and an anti-cholinergically active substance
- c. a combination of a dopamine agonist and an NMDA receptor antagonist
- d. a combination of L-dopa and an NMDA receptor antagonist
- e. a combination of a dopamine agonist or L-dopa, an anti-cholinergically active substance, and an NMDA receptor antagonist
- f. a combination of a dopamine agonist or L-dopa, an anti-cholinergically active substance and a monoamine oxidase B inhibitor
- g. a combination of a dopamine agonist, an anti-cholinergically active substance, and a sympathomimetics
- h. a combination of L-dopa, an anti-cholinergically active substance, and a sympathomimetics
- i. a combination of a dopamine agonist, an NMDA receptor antagonist, and a sympathomimetics

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j. a combination of L-dopa, an NMDA receptor antagonist, and a sympathomimetics

k. a combination of a dopamine agonist, an anti-cholinergically active substance, and catechol-o-methyl transferase inhibitor

l. a combination of L-dopa, an anti-cholinergically active substance and catechol-o-methyl transferase inhibitor

m. a combination of a dopamine agonist, an NMDA receptor antagonist and catechol-o-methyl transferase inhibitor

n. a combination of L-dopa, an NMDA receptor antagonist and catechol-o-methyl transferase inhibitor

o. a combination of a dopamine agonist, an anti-cholinergically active substance, and a decarboxylase inhibitor

p. a combination of L-dopa, an anti-cholinergically active substance and a decarboxylase inhibitor

q. a combination of a dopamine agonist, an NMDA receptor antagonist and a decarboxylase inhibitor

r. a combination of L-dopa, an NMDA receptor antagonist and a decarboxylase inhibitor

s. a combination of a dopamine agonist, an anti-cholinergically active substance, and beta blocker

t. a combination of L-dopa, an anti-cholinergically active substance and beta blocker

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u. a combination of a dopamine agonist, an NMDA receptor antagonist and a beta blocker

v. a combination of L-dopa, an NMDA receptor antagonist and a beta blocker

w. selegiline and rotigotine

**Depending on the specific combination of active agents selected above, Applicant is required to elect a specific species within the genus below.**

**Specific dopamine agonist**

a. lisuride

b. bromocriptine

c. pramipexol

d. ropinirole

e. rotigotine

f. terguride

g. carbergoline

h. apomorphine

i. piribedile

j. pergolide

k. PHNO

**Specific anti-cholinergics**

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- a. bipreriden
- b. trihexyphenidyl
- c. procyclidine
- d. bornaprine
- e. metixene
- f. orphenadrine
- g. scopolamine
- h. atropine and other belladonna alkaloids
- i. benztropine
- j. nicotine

**NMDA receptor antagonist**

- a. memantine
- b. amantadine

**Specific beta blocker**

- a. propranolol
- b. timolol
- c. pindolol
- d. atenolol

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: There are no generic claims presented.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: there is no special technical feature in the claims. The independent claim possesses numerous alternatives for the active agents none of which are carried throughout the claims. Applicants attention is directed to US Patent 5,877,173 to Olney et al, which discloses the transdermal administration of an NMDA receptor antagonist co administered with lisuride, which is a dopamine inhibitor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615